REMARKS

Claims 18, 19 and 21 had been previously added. Claims 1-19 and 21 are now pending in this application. Claims 18, 19 and 21 have now been amended to be consistent with the compositions of originally presented and examined claims 1, 9, 10, 14 and 17. Accordingly Applicant requests full consideration of claims 18, 19 and 21 as being directed to the same elected invention as claims 1, 9, 10, 14 and 17. Full reconsideration is requested.

Claims 2-8, 11-13 and 15-16 stand withdrawn from further consideration as being directed to non-elected subject matter. Therefore, claims 1, 9, 10, 14, 17-19 and 21 remain in the application for full consideration.

Claims 1, 9, 10 now stand rejected under 35 U.S.C. 112, second paragraph, as purportedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has therefore amended claim 1 to remove the double inclusion of bicarbonate. Withdrawl of the Examiner's 35 U.S.C. 112 rejection is therefore requested.

Before commencing any rebuttal with reference to any alleged prior art the Examiner is respectfully directed towards the following excerpted case law from which Applicant will draw liberally.

ANTICIPATION

The following excerpts of U.S. case law represent Applicant's understanding of the test for novelty and obviousness.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986) ("It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention, and that such a determination is one of fact.").

In re Donohue, 766 F.2d 531, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985) ("an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.").

In Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1574, 224 U.S.P.Q. 209, 411 (Fed. Cir. 1984) ("exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference").

In Tights, Inc. v. Acme-McCrary Corp., 541, F.2d 1047, 191 U.S.P.Q. 305 (4th Cir. 1976); Saf-Gard Prods., Inc. v. Service Parts, Inc., 532 F.2d 1266, 190 U.S.P.Q. 455 (9th Cir. 1976); Shanklin Corp. v. Springfield Photo Mount Co., 521 F.2d 609, 187 U.S.P.Q. 129 (1st Cir. 1975) ("To anticipate under section 102, a prior art reference must disclose all the elements of the claimed invention or their equivalents functioning in essentially the same way.").

In re Beno (1985) 768 F.2d 1340, 226 U.S.P.Q. 683 (Fed. Cir. 1985) a prior art patent or published application is a reference only for that which it teaches.

In re Sun, 31 USPQ 2d 1451, 1453 (Fed. Cir. 1993) (unpublished)

Under section 102(b), anticipation requires that the prior art reference disclose, either expressly or under the principles of inherency, every limitation of the claim. . . .

But to be prior art under section 102(b), a reference must be enabling. . . . That is, it must put the claimed invention in the hand of one skilled in the art. . . . The examiner bears the burden of presenting at least a prima facie case of anticipation.

Helifix Ltd. v. Blok-Lok, Ltd., 54 USPQ 2d 1299, 1304 (Fed. Cir. 2000)

"[E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Donohoe*, 766 F.2d at 533, 226 USPQ at 621.

In re Wilder, 166 USPQ 545, 548 (C.C.P.A. 1970)

Simply stated, a prior publication or patent description will be considered as anticipatory when its disclosure is at once specific and enabling with regard to the particular subject matter at issue. . . . However, such disclosure may yet be held not to legally anticipate the claimed subject matter if it is found not to be sufficiently enabling, in other words, if it does not place the subject matter of the claims within "the possession of the public."

Ciba-Geigy Corp. v. Alza Corp., 37 USPQ 2d 1337, 1341 n.3 (Fed. Cir. 1995) (unpublished)

An anticipatory reference must be enabling, *see Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479, 1 U.S.P.Q.2D (BNA) 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909, 96 L. Ed. 2d 382, 107 S. Ct. 2490 (1987), so as to place one of ordinary skill in possession of the claimed invention. *In re Spada*, 911 F.2d 705, 708, 15 U.S.P.Q.2D (BNA) 1655, 1657 (Fed. Cir. 1990); *see Seymour v. Osborne*, 78 U.S. 516, 555, 20 L. Ed. 33 (1870) ("The knowledge supposed to be derived from the publication must be sufficient to enable those skilled in the art or science to understand the nature and operation of the invention.").

OBVIOUSNESS

The traditional test enunciated in Graham vs. John Deere Company 383 U.S. 1, 148 U.S.P.Q. 459 1966, for Section 103 nonobviousness requires the fact finder to make several determinations. The test provides that the scope and content of the prior art be determined, the differences between the prior art and the claims at issue be ascertained, and the level of ordinary skill in the pertinent art be resolved. Thus, the patentability of the claims at hand must stem from the fact that the specific combination of the claimed elements was not disclosed in the prior art and the additional allegation that the specific combination of claimed elements was nonobvious to one of ordinary skill in the art.

Clearly, the prior art does not suggest or provide any reason or motivation to make such a modification as purported by the Examiner. With reference to In Re: Regal, 526 F. 2d 1399, 1403 n. 6, 188 USPQ 136, 139 n. 6 (CCPA 1975).

> "There must be some logical reason apparent from positive, concrete evidence of record which justifies a combination of primary and secondary references".

In Re: Geiger, 815 F. 2d 686, 688, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987) (obviousness can not be established by combining pieces of prior art absence some "teachings, suggestion, or incentive supporting the combination"): In Re: Cho. 813 F. 2d 378, 382, 1 USPQ 2d 1662, 1664 (Fed. Cir. 1987)("discussing the Board's holding that the artisan would have been motivated to combine the references").

Therefore, it Applicant's view there is no evidence of motivation in the prior art, either within the references themselves, or knowledge generally available to one of ordinary skill in the art, to make the purported changes suggested by the Examiner to arrive at the claimed subject matter.

Respectfully, the Examiner is creating a 20/20 hindsight reconstruction using Applicant's invention as a blue print to allegedly find elements of Applicant's combination in the prior art. This is not permissible as set out below.

In re Oetiker, 24 USPQ 2d 1443, 1446 (Fed. Cir. 1992)

The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a prima facie case of obviousness. **There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination.** (emphasis added)That knowledge can not come from the applicant's invention itself.

ATD Corporation v. Lydall, Inc., 48 USPQ 2d 1321, 1329 (Fed. Cir. 1998)

Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. **There must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor.(emphasis added)**

In Re: Fritch, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992)

> "Wilson and Hendrix fail to suggest any motivation for, or desirability of, the changes espoused by the Examiner and endorsed by the Board. Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. **It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious**(emphasis added). The court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and

choose among isolated disclosures in the prior art to deprecate the claimed invention."

Claims 1, 9, 14 and 17 now stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Purcell et al. (US 5,945,449). The Examiner purports that Purcell et al. explicitly discloses a sterile calcium-free bicarbonate concentrate comprising 86.87 ± 8.6 g/l NaCl, 2.05 ± 0.2 g/l $MgCl_2$, and 39.69 ± 3.9 g/l $NaHCO_3$ and a sterile, diluted solution, wherein 140 ± 14 mM Na, 0.75 ± 0.07 mM Mg, 106.5 ± 10 mM Cl, and 35 mM ± 3.5 HCO_3 are present. However, Applicant has now amended the present claim set to limit the upper limit of bicarbonate to 27.5 mmol/L. This level is not taught in Purcell nor would it be enabled by the teaching of Purcell nor obvious to do so! A practitioner cannot and would not merely adjust the bicarbonate level by dilution since this effort would also effect the other electrolyte ions to the detriment of any patient including the risk of death.

Referring to US Patent 5,945,449 to Purcell there is taught a sterile solution containing 35.0 ± 3.5 mmol/L of bicarbonate. At no time does Purcell teach a bicarbonate level of less than 31.5 mmol/L. However the present invention rests in the discovery and the implementation thereof that addresses and seeks to maintain normal bicarbonate levels of approximately 25 mmol/L. When an anticoagulant such lactate or citrate is added to the dialysis solution the liver will convert the weak acid to bicarbonate. The present dialysis solution provides for an allowance of this fact wherein the original NORMOCARB® 35 did not. By providing a sterile dialysis solution having a bicarbonate level of from 5 to 27.5 mmol/L an accommodation is made for the conversion in the liver of the weak acid to bicarbonate which is not contemplated in Purcell. Therefore Purcell cannot be considered as enabling as per the above-mentioned case law. Further there is no motivation in Purcell to do so. As found in the current disclosure and particularly the summary of the invention the use of a low bicarbonate dialysis solution of the invention takes into account any bicarbonate derived from the weak acid if used as an anticoagulant, for example citrate. Thus metabolic complications are effectively minimized. The benefit of such a low concentration of bicarbonate of for example 25 mmol/L is that if the patient's bicarbonate level drops below this level, bicarbonate diffuses from the dialysate across the semi-permiable membrane to the patient correcting the problem. If there is an excess of bicarbonate in the blood (metabolic alkalosis), then bicarbonate will diffuse out into the dialysate and be removed from the blood returning the patient toward the normal level. In some patients, excessive bicarbonate may result in alkalemia whereas in some patients insufficient bicarbonate may result in acidemia. The

present invention includes a sterile calcium-free low bicarbonate concentrate containing magnesium, sodium chloride and a low concentration of bicarbonate that can be used in a number of novel applications, for example continuous renal replacement therapies, such as continuous dialysis and hemofiltration. The Examiner is referred to the disclosure for more particulars with respect to the advantages of the present invention.

At no time however did Purcell contemplate providing a low bicarbonate concentrate for the purposes described above to accommodate for the conversion of the weak acid to bicarbonate in the liver. Therefore Purcell is not enabling. Further there is no motivation in Purcell to do so since Purcell did not even appreciate the problem which Applicant had discovered. In fact none of the other references and inventors appreciated this problem.

The inventor of the present application is Dr. Sheldon Tobe, M.D., who is an Associate Professor of Medicine at the University of Toronto and currently is the Staff Nephrologist at the Sunnybrook Health Science Center in Toronto, Ontario. Dr. Tobe has reviewed Purcell and the other prior art cited within the Examiner's Report and we attach hereto his comments in the form of a Declaration from an expert which Declaration is hereby incorporated by reference in its entirety in this response as if the comments were made directly herein. Although the bicarbonate solution of Purcell is mixed in a ratio of 80ml ± 1ml of concentrate to 1L of sterile physiologically exceptable diluent, such as water, the net result of the solution is a bicarbonate of 35.0 ± 3.5 mmol/L or a 10% leeway in either direction. In Dr. Tobe's opinion the instructions are pretty specific and the concentrate should be diluted exactly as described without going more than 10% in either direction. In fact going more than 10% in either direction may become fatal if used in a dialysis regimen. This is because all of the other electrolytes besides bicarbonate would be diluted as well and the dialysis solution namely NORMOCARB® is designed for exactly the specified dilution as discussed above namely 80ml to 1L. If the original NORMOCARB® 35 were diluted, in an attempt to create a bicarbonate of 25 mmol/L, this would result at a concentration of 71.43% of the original NORMOCARB® 35 thereby reducing the sodium from 140 to 100 and the chloride from 106.5 to 76.1. In Dr. Tobe's expert opinion the resulting solution alleged by the Examiner as being an obvious variation would not be safe for use and might likely result quickly in the death of a patient. Diluting the overall solution without adjusting each component for the specific use, namely the condition being treated, would be totally unacceptable from a medical perspective. The Examiner is entirely incorrect, respectfully, that merely adding a bit

of fluid to the concentrate to adjust and obtain a low bicarbonate would be easily accomplished. This ignores that the resulting sodium of 100 would be entirely unacceptable. Dr. Tobe also says that it's not inherent in the Purcell concentrate to so dilute that concentrate to result in a bicarbonate of 25 mmol/l. He has even stated in his Declaration that in doing so a physician may be faced with a malpractice suit. Further Dr. Tobe has stated that he would not approve the use of NORMOCARB® 35 for this application. Dr. Tobe further states that any attempt to dilute the bicarbonate to a level of 5 mmol/l results in a ludicrous result of sodium of approximately 20 which would frankly be toxic and hemolize the red cells on contact. Respectfully the Examiner does not understand the technology and has clearly misread the original Purcell patent which clearly cannot be considered as enabling in view of Dr. Tobe's opinions.

The claims have now been amended to identify over Purcell in the broadest sense to be limited to the range of 5 to 27.5 mmol/L of bicarbonate which is not contemplated in Purcell since Purcell only teaches a bicarbonate lower limit of 31.5 mmol/L.

It is therefore requested that the Examiner reconsider his rejection of the claims on the basis of Purcell since the ion concentration of the present invention is different and clearly for a different purpose namely to compensate for the conversion of weak acids to bicarbonate in the liver. Purcell did not make this compensation part of his invention and clearly it is not evident from the teachings of Purcell to do so. Although the Purcell composition is suitable for hemodialysis and peritoneal dialysis the properties of the actual concentrate and dialysis solution are quite different. Therefore all of Applicants claimed features are absent from Purcell and the claims cannot be anticipated especially in view of the present amendments, as is a requirement specified in the above-mentioned jurisprudence précised above. According to accepted jurisprudence for a reference to anticipate it must be enabling and include each and every limitation of the claims. This is not the case in view of the present amendments and the above-mentioned arguments and full reconsideration is requested and withdrawl of the Examiner's rejection is also further appreciated.

Out of an abundance of caution it is surmised the Examiner might also cite Purcell as a reference to allegedly render obvious the claims of the present application. For the same reasoning described above this cannot be the case since there is no motivation within Purcell to one skilled in the art to arrive at Applicant's present amended claim set. According to the

accepted jurisprudence of Graham v. John Deere, Applicant has set out the differences between the present claim set as amended and the prior art and has established that the claims result in more than anything that might have been contemplated by Purcell. Full reconsideration is respectfully requested.

Claim 17 now stands rejected under 35 U.S.C. 102(e) as being allegedly anticipated by Mahiout (US 6,492,336). The Examiner alleges that Mahiout explicitly discloses Applicant's invention. Claim 17 of the present invention has therefore been amended to include the calcium free limitation and full reconsideration is therefore requested.

Referring now to Mahiout (US 6,492,336) hereinafter referred to as Mahiout, the Examiner has admitted that the calcium-free feature which was described in the other claims is not recited in claim 17. For the same reasoning, therefore as previously presented in the prior response the reasoning thereof being incorporated by reference in its entirety, it is therefore submitted that claim 17 as amended is now allowable over the prior art and specifically the Mahiout reference.

Claim 14 now stands rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Koo et al. (previously cited as Chemical Abstracts 124:325351). The Examiner alleges that Koo et al. explicitly disclose a calcium-free dialysate, which contains 30 mM bicarbonate, at a pH 7.8. Applicant has therefore limited claim 14 to a bicarbonate level in the range 5 to 27.5 mmol/L, which Koo does not teach. Reconsideration is respectfully requested.

Referring now to Koo, the Examiner has stated that the sterile feature would have been necessarily present in a dialyisate for hemodialysis. Dr. Tobe however disagrees with this statement since these compositions are not sterile. One of the problems in sterilizing dialysate is by adding heat the ion concentration is altered. The present dialysis concentrate is in fact sterilized by cold filtering. Further the Examiner has stated that the Koo reference has the exact composition ingredients of the present invention and alleges that the same properties must necessarily be present concluding that the claim is somehow anticipated. Dr. Tobe disagrees and the Examiner is directed to his comments in his Declaration which is incorporated by reference in its entirety into this response as if it were included herein.

Claims 1, 9, 10, 14 and 17 also stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Koo et al. The Examiner alleges that Koo et al. discloses a calcium-free hemodialysis solution. Perhaps, without making such an admission, but Koo does not teach a bicarbonate level in the range of 5 to 27.5 mmol/L.

However, in Dr. Tobe opinion the Koo paper describes a calcium-free dialysate for intermittent hemodialysis. Their dialysate is not sterile because they are using concentrates with classic intermittent dialysis machines. The Examiner has stated that the sterile feature would have been necessarily present in a dialysate for hemodialysis. This is not the case. There is nothing in the Koo paper to suggest that this was the case. The Koo paper uses a concentrate to make up a dialysis solution from a standard commercially available calcium dialysate that was known. The Examiner discusses sterile features necessarily being present in the Koo teaching but this is not the case. It is not a simple matter to sterilize a bicarbonate concentrate. It cannot be heat sterilized since the magnesium present will precipitate into insoluable crystals. Therefore Applicant cold filters the concentrate in order to sterilize it. The present invention refers to a calcium-free dialysis concentrate which may be diluted following the instructions provided resulting in a dialysate of exactly the correct concentration of sodium bicarbonate, chloride and magnesium and which is also sterile. Further the resulting bicarbonate is in the range of 5 to 27.5 mmol/L. Koo does not teach this limitation and therefore cannot be considered to render the claims obvious. The Examiner alleges that one skilled in the art would have been motivated to provide a sterile dialysis concentrate or solution in order to ensure patient safety. However in carrying out the instructions of the Examiner to dilute the concentrate beyond the recommended levels one skilled in the art is placing the patient at considerable risk. The Examiner in preparing his obviousness rejection has relied considerably on the ability of one skilled in the art to choose sodium chloride, magnesium chloride and sodium bicarbonate and prepare a dialysate with the required ions. The Examiner then further alleges that Koo teaches a concentration of 30 mmol/L. However, he also suggests that one skilled in the art would have in reviewing the Koo dialysate be motivated to modify the bicarbonate concentration and still expect successful treatment of hypercalcemia. The Examiner refers to the term "slightly" but this is not correct since the modification and the motivation to do so is clearly lacking in the art. Why would one skilled in the art, namely a Nephrologist modify the concentration "slightly" with the full knowledge that these ions are critical to the individual patient and therefore must be carefully balanced in the solution. To provide a "similar" ion content and make-up is

unacceptable. The criticality of getting the ion concentration correct is established with the present invention. Further by making the alleged "slight" modifications of bicarbonate content the other ions are thrown out of balance and one would never use such a dialysate. Applicant respectfully submits therefore that the Examiner's rejection of the claims as obvious in view of Koo have been overcome by argument and amendments and full reconsideration is requested.

Claims 1, 9, 10, 14 and 17 now stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Martis et al. (WO 96/01118) in view of Purcell et al. The Examiner alleges that Martis et al. discloses a peritoneal dialysis solution. Applicant agrees. But Martis does not teach a dialysis solution for continuous renal replacement therapy which is an all together different process. The claims are now limited to such a process. Further the Examiner is advised that Martis in fact teaches an effective bicarbonate level of over 30 mmol/L since the weak acid incorporated in Martis will be converted by the liver to bicarbonate at a one to one conversion rate. Therefore Martis in fact includes effective bicarbonate levels of 30 to 50 mmol/l which clearly is well above the upper limit of 27.5 mmol/L provided in Applicant's amended claim set. Please refer to Dr. Tobe's comments in that regard.

Referring now to Martis (WO 96/01118) hereinafter referred to as Martis, the Examiner alleges that the bicarbonate level is in the range of 20 to 30 mEq/L without taking notice that a weak acid is provided in the range of 10 to 20 mEq/L which as discussed above and would be converted to bicarbonate in the liver. Applicant submits that in fact the range of calcium and magnesium in the Martis composition must be zero or it will not operate since calcium bicarbonate will precipitate as soon as the dialysate is introduced. Further Martis discusses a peritoneal dialysis solution only and provides for the weak acid which might be lactate, pyruvate, citrate, isocitrate, etc. Referring to Martis there is taught the step of administering to the patient of a weak acid present in the solution in an amount that offsets the daily hydrogen production of a approximately 1 mEq/kg per day. This is an admission of Martis in the mind of Dr. Tobe that the purpose of the weak acid is to be metabolized into something that offsets daily hydrogen production namely it is metabolized to bicarbonate. This teaching of Martis includes a solution having 20 to 30 mmol/L of bicarbonate, but the Examiner fails to recognize that the 10 to 20 mmol/L of the weak acid gets converted directly to bicarbonate, yielding a range of effective bicarbonate from 30 to 50 mmol/L which is well beyond the range of 5 to 27.5 mmol/L in the present claims. Martis does not contemplate a total

bicarbonate equivalent level of below 27.5 mmol/L since the minimum level of bicarbonate and bicarbonate equivalents as taught in Martis is 30 mmol/L and above.

Since Martis teaches only peritoneal dialysis it is respectfully submitted that the teachings of Martis are not relevant to the present claim set. One concern Dr. Tobe has with respct to Martis is the calcium level of the solution specified having a range from 0.0 to 4.0. Each of the examples that Martis provides include a calcium of 3.5 mEq/L. This is the standard calcium concentration in peritoneal dialysis solution. Theoretically a peritoneal dialysis solution could have a calcium level of 0. Dr. Tobe is unaware of any commercially available solutions that have a calcium of 0. As peritoneal dialysis solution is typically used for chronic dialysis, calcium in the solution of 0 mEq/L would lead to chronic lose of calcium and would need regular supplementation. A solution with 0 calcium however would not lead to any precipitation with bicarbonate. Adding any calcium to the peritoneal dialysis solution described by Martis that also contains bicarbonate to minimum of 20 mmol/L would lead to precipitation between calcium and bicarbonate. This would particularly occur in the sterilization phase which generally involves heat. The only situation covered by Martis in which this would not occur is if the weak acid was citrate in which case citrate would chelate the calcium and likely prevent precipitation with bicarbonate. This situation is not covered in the disclosure by Martis. Also a peritoneal dialysis solution containing citrate would not deliver calcium to the patient but might also chelate the patient's calcium leading to low calcium levels in the patient and clinical problems due to the low calcium levels. Martis does not present evidence that they have been able to create a solution that has both bicarbonate and calcium that does not precipitate or that they have clinical evidence that a solution with no calcium would be safe. Therefore one must conclude that Martis is not enabling in this regard and would not provide sufficient motivation to one skilled in the art to arrive at Applicant's invention.

Peritoneal dialysis is a continuous form of dialysis. However it is a form of chronic dialysis performed at home for patients with chronic renal failure. It is rarely used in the intensive care setting. In this form of dialysis the solution is applied to the abdomen of the patient and it dwells for a period of time to allow the diffusive exchange of toxins which are removed from the patient. As well, to improve the patient's acid-base balance bicarbonate equivalents from the solution diffuse into the patient.

Specifically NORMOCARB® 25 was designed for patients who have reached normal levels of bicarbonate. The principle of maintaining a bicarbonate level around the normal physiologic level of 25 is an important principle. If the body's bicarbonate level rises above 25, bicarbonate will diffuse into dialysate. If the body's bicarbonate drifts below 25 bicarbonate will be added to it from the dialysate. This principle also works for the other electrolyte components available in NORMOCARB® 25.

Referring now to the Examiner's allegations with respect to Martis in view of Purcell, what would Martis in fact glean from Purcell. The motivation is lacking in Purcell to provide a dialysis solution in the range of 5 to 27.5 mmol/L. This motivation is also lacking in Martis. How then, could the Examiner's alleged combination result in an effective bicarbonate concentration of 5 to 27.5 mmol/L, again taking into consideration that the weak acid converts in the liver to bicarbonate equivalents. The Examiner freely admits that the composition make-up of Purcell is different and he relies on the knowledge of one skilled in the art to provide a sterile dialysis solution within the range of Applicant's limitations currently provided in his amendments. The Examiner's alleged combination of Martis in view of Purcell would still fall significantly short of Applicant's amended claims and therefore the claims are most assuredly, as amended, novel and inventive. Full reconsideration is therefore requested.

The test for novelty is found In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986) ("It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention, and that such a determination is one of fact."). Clearly none of Mahiout, Purcell, Koo, or Martis therefore are anticipatory under the meaning of the statute, nor are they enabling.

The examiner bears the burden of presenting at least a prima facie case of anticipation. "[E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Donohoe*, 766 F.2d at 533, 226 USPQ at 621. An anticipatory reference must be enabling, *see Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479, 1 U.S.P.Q.2D (BNA) 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909, 96 L. Ed. 2d 382, 107 S. Ct. 2490 (1987), so as to place one of ordinary skill in possession of the claimed invention. *In re Spada*, 911 F.2d 705, 708, 15 U.S.P.Q.2D (BNA) 1655, 1657 (Fed. Cir. 1990); *see Seymour v. Osborne*, 78 U.S. 516, 555, 20 L. Ed. 33 (1870)

("The knowledge supposed to be derived from the publication must be sufficient to enable those skilled in the art or science to understand the nature and operation of the invention."). Under section 102(b), anticipation requires that the prior art reference disclose, either expressly or under the principles of inherency, every limitation of the claim.. But to be prior art under section 102(b), a reference must be enabling. . . . That is, it must put the claimed invention in the hand of one skilled in the art. . Clearly none of Mahiout, Purcell, Koo, or Martis therefore are enabling with respect to the amended claim set under the meaning of the statute.

It is submitted that none of the references anticipate the pending claim set since they do not meet each and every limitation in the amended claim set as required by law. Full reconsideration is requested.

The traditional test enunciated in Graham vs. John Deere Company 383 U.S. 1, 148 U.S.P.Q. 459 1966, for Section 103 nonobviousness requires the fact finder to make several determinations. The test provides that the scope and content of the prior art namely Koo, Martis, Purcell and Mahiout be determined, the differences between the prior art namely Koo, Martis, Purcell and Mahiout and the claims at issue be ascertained, as setout in the Declaration of Dr. Tobe, and the level of ordinary skill in the pertinent art be resolved. Thus, the patentability of the claims at hand stems from the fact that the specific combination of the claimed elements was not disclosed in Koo, Martis, Purcell and Mahiout or any combination thereof and the additional allegation that the specific combination of claimed elements was nonobvious to one of ordinary skill in the art as argued herein and supported by Dr. Tobe's Declaration .

Clearly, the prior art does not suggest or provide any reason or motivation to make such a modification as purported by the Examiner. With reference to In Re: Regal, 526 F. 2d 1399, 1403 n. 6, 188 USPQ 136, 139 n. 6 (CCPA 1975).

> "There must be some logical reason apparent from positive, concrete evidence of record which justifies a combination of primary and secondary references".

In Re: Geiger, 815 F. 2d 686, 688, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987) (obviousness can not be established by combining pieces of prior art absence some "teachings, suggestion, or incentive supporting the combination"): In Re: Cho. 813 F. 2d 378, 382, 1 USPQ 2d 1662,

1664 (Fed. Cir. 1987)("discussing the Board's holding that the artisan would have been motivated to combine the references").

Therefore, it Applicant's view there is no evidence of motivation in the prior art, either within the references themselves, or knowledge generally available to one of ordinary skill in the art, to make the purported changes suggested by the Examiner to arrive at the claimed subject matter.

Respectfully, the Examiner is creating a 20/20 hindsight reconstruction using Applicant's invention as a blue print to allegedly find elements of Applicant's combination in the prior art. This is not permissible as set out below.

In Re: Fritch, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992)

> "Wilson and Hendrix fail to suggest any motivation for, or desirability of, the changes espoused by the Examiner and endorsed by the Board. Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. **It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious**(emphasis added). The court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."

In view of applicant's submissions full reconsideration of all allegations of anticipation and obviousness is respectfully requested. It is submitted that all issues have been addressed herein by amendment and rebuttal including expert evidence and a Notice of Allowance is appreciated.

Lastly the Examiner reminds applicant about his duty to disclose "all information known to be material to patentability" in this application with respect to NORMOCARB® product information. The Examiner is advised that NORMOCARB® owned by the Assignee was marketed originally by the Assignee consistent with the teachings of Purcell and was based on those teachings. Applicant had previously advised the Examiner of this fact.

If any questions arise, the Examiner is respectfully requested to contact Neil Hughes at (905) 771-6414 at the Examiner's convenience.

Respectfully submitted,

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Agent for the Applicant

NHH/lvp